NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KING PHARMACEUTICALS, INC., KING PHARMACEUTICALS RESEARCH AND DEVELOPMENT, INC., AND PHARMACEUTICAL IP HOLDING, INC., Plaintiffs, v. SANDOZ, INC., Defendant.	)	Civil Action No. 08-5974 (GEB) **MEMORANDUM OPINION** **PUBLIC VERSION**

This matter comes before the Court on Plaintiffs' renewed motion for judgment as a matter of law or for a new trial. (Doc. No. 357). This patent case was tried to a jury, which returned a verdict that the patent was invalid and Defendants did not infringe that patent. Plaintiffs filed their motion on October 18, 2010, (Doc. No. 357), Defendants filed an opposition on November 19, 2010, (Doc. No. 363), and Plaintiffs filed their reply on December 6, 2010. (Doc. No. 367). The Court has considered these submissions without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons stated below, the Court finds that there was sufficient evidence to support the jury's verdict that the patent was invalid because it was obvious and denies Plaintiffs' motion.

I. BACKGROUND

This Hatch-Waxman patent litigation began on December 5, 2008, when King filed a complaint alleging that Sandoz filed an Abbreviated New Drug Application ("ANDA") seeking approval to engage in the commercial manufacture, use, sale, or importation of 800mg metaxalone tablets that are allegedly covered by King's patent, U.S. Patent No. 7,122,566 ("the '566 patent"). (Compl. at ¶ 13). On March 30, 2010, Sandoz received FDA approval to market their generic metaxalone product and began an at-risk launch. This Court denied Plaintiffs' motion for a preliminary injunction, (Doc. No. 121), and the case proceeded to trial. The parties tried the case before a jury from September 7, 2010, to September 16, 2010. At the conclusion of the trial, the jury found that all of the asserted claims of the patent were invalid and that Sandoz did not infringe them. (Doc. Nos. 344-45, 349). The Court entered judgment consistent with that verdict. (Doc. No. 346).

A. Facts

The facts, in the light most favorable to Defendants are these:

This patent infringement case involves the '566 patent, which claims a method of treatment for patients using metaxalone. The inventor of the patent, Dr. Richard A. Roberts, testified that he conceived the invention no earlier than July 2005 while taking a shower. (Sept. 7, 2010 Trial Tr. at 85). Claim 1 is representative of the issues of this case, as both parties acknowledge. (Pls.' Br. at 2-3; Def.'s Br. at 5). Claim 1 provides:

> 1. A method of using metaxalone for treating a patient's condition comprising:
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> providing a patient with metaxalone; and
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> informing the patient or a medical care worker that metaxalone affects the activity of a cytochrome p450 isozyme, and that administration of metaxalone

> with a substance that affects activity of cytochrome p450 isozyme can affect plasma concentration, safety, efficacy or any combination thereof of metaxalone, the substance, or both.

('566 patent, 64:47-56). Metaxalone is not a new drug; indeed, it has been marketed and used for more than 50 years. (*See* PTX 1). Consequently, the first step, "providing" the patient with metaxalone is not new; (*see* Sept. 7, 2010 Trial Tr. at 127), it is the "informing" step that allegedly adds new matter to the art. The informing step involves telling the patient that metaxalone affects cytochrome p450 and that its administration with another substance that affects cytochrome p450 can change the effects or effectiveness of metaxalone or the other substance. ('566 patent, 64:47-56). Thus, the invention focuses on imparting this new information about cytochrome p450.

Prior to Dr. Roberts' invention, quite a bit of knowledge was available about the cytochrome p450 system and metaxalone's metabolism. Plaintiffs' expert Dr. Guengerich testified that as far back as 1966, the person of skill in the art knew that metaxalone was metabolized by oxidation, that most metabolism by oxidation occurs in the liver, and that 85% of liver metabolism uses the cytochrome p450 system. (Sept. 8, 2010 Trial Tr. at 133-136; *see also* Sept. 7, 2010 Trial Tr. at 85-87). The 2003 Skelaxin drug label also disclosed that metaxalone could impair a patient's ability to function if taken with a CNS depressant or alcohol, which Dr. Guengerich opined may have been due to the p450 system. (*Id.* at 140-42).

Further, information was available about the role of cytochrome p450 in drug metabolism, particularly in two guidances issued by the FDA. In 1997 and 1999, the FDA set forth two guidances, one which was an intended to be a complement to the other (collectively "the FDA Guidances"). The Guidances recommend that drug manufacturers incorporate the results of cytochrome p450 testing on their package inserts. (DTX 52 at 13-16). In the

"Techniques and Approaches for Studies In Vitro of Drug Metabolism and Drug Interactions," the FDA Guidances also explicitly set forth how to carry out *in vitro* studies to determine either: (1) which p450 enzymes the body uses to metabolize a drug, or (2) which p450 enzymes are induced and inhibited by a drug. The Guidances explain that these tests are "exceptionally rapid and straight forward" as well as "inexpensive and readily carried out." (DTX 51 at 6, 7). While these Guidances were primarily directed toward new drug applications, (*see* DTX 52 at 1), they also provided for testing of drugs already on the market in order to determine drug-drug interactions.[1] (DTX 52 at 3, 5, 11; Sept. 15, 2010 Trial Tr. 31-33).

The FDA Guidances teach that when two substances are metabolized by the same cytochrome p450 pathways, "the potential for a drug inhibiting the metabolism is almost always present," and that it may also be present for different pathways. (DTX 51 at 4).

Against this backdrop, Dr. Roberts ordered cytochrome p450 testing on metaxalone. The testing that provided the information disclosed by the invention was not conducted by Dr. Roberts himself, but by In Vitro Technologies ("IVT"), a third-party testing company that routinely performed this type of testing. (*See* Sept. 8, 2010 Trial Tr. at 146; Sept. 7, 2010 Trial Tr. at 86). Dr. Roberts asked IVT to take metaxalone and conduct tests on its interaction with the predominant p450 enzymes involved in drug metabolism. (Sept. 7, 2010; Trial Tr. at 146-47). IVT prepared the protocols, the written procedures for the studies, and chose the p450 enzymes that were known to be predominantly involved in drug metabolism. (*Id.* at 146-47, 164-65). Dr. Roberts relied upon IVT's expertise to develop these protocols. (*Id.* at 164-65).

[1] Neither parties' definition of a person of ordinary skill in the art limited that person's field to new drugs and so the jury could have concluded that a person of ordinary skill would have been aware of these statements and been able to apply them to older drugs. In addition, there is nothing about the distinction between old drugs and new drugs that would suggest that cytochrome p450 is more likely to be involved in the metabolism of new drugs than it is of old drugs. Thus, the person of ordinary skill would have realized that the Guidances applied to old drugs as well.

IVT also performed work to develop a method to detect metaxalone for the studies. (*Id.* at 160-163). IVT conducted the tests and produced a series of reports about the results because they had the equipment and expertise to run the studies. (*Id.* at 143-47; Trial Tr. at 116, Sept. 15, 2010 (reading in the June 17, 2010 Dep. Tr. at 277)).

At the time of the invention it was also known in the art that the p450 enzymes that IVT tested for were involved in drug metabolism. The Background section of the '566 patent, which explains the prior art, explains that "Cytochrome p450 isozymes identified as important in active agent metabolism are CYP1A2, CYP2A6, CYP2B6, CYP2C9, CYP2C19, CYP2D6, CYP2E1, and CYP3A4." ('566 patent, 2:31-33). Dr. Guengerich, an expert for the Plaintiffs, agreed that the isozymes tested by IVT were known to be involved in drug metabolism because of papers published by the Pfizer and Amgen groups. (Trial Tr.at 152-153, Sept. 8, 2010).

II. DISCUSSION

While Plaintiffs do not take issue with the Court's charge to the jury, they nonetheless argue that the jury could not reasonably have found against them because no reasonable jury could have found that the patent was invalid and no reasonable jury could have found that Sandoz did not infringe the patent. Specifically, Plaintiffs argue that no reasonable jury could have found that the invention of the '566 patent was anticipated by prior art because the alleged anticipating reference does not disclose the "informing step" of its invention. (Pls.' Br. at 7-10). Plaintiffs further argue that no reasonable jury could have found that the '566 patent was obvious because the prior art did not disclose any method of treatment or suggest combining references to perform p450 testing with metaxalone. Plaintiffs also suggest that secondary factors militated against a finding of obviousness. (Pls.' Br. at 10-17). Finally, Plaintiffs argue that no reasonable

jury could have found that Sandoz did not infringe directly or indirectly. (Pls.' Br. at 17-23). For these reasons, Plaintiffs ask that the Court award judgment as a matter of law or a new trial.

The Court finds that there was sufficient evidence of obviousness to support the jury's verdict of invalidity. As a result, the Court upholds the jury verdict and will not reach the other issues presented in the motion.

A. Standard of Review

Plaintiffs' motion for judgment notwithstanding the verdict is considered on the same standard as a judgment as a matter of law. *Starceski v. Westinghouse Elec. Corp.*, 54 F.3d 1089, 1093 (3d Cir. 1995). A court should set aside the verdict "only if, as a matter of law, the record is critically deficient of that minimum quantity of evidence from which a jury might reasonably afford relief." *Trabal v. Wells Fargo Armored Serv. Corp.*, 269 F.3d 243, 249 (3d Cir. 2001). The motion should be granted "only if, viewing the evidence in the light most favorable to the non- movant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find" for the non-movant. *Lighting Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993). "In considering a motion for judgment n.o.v., a court is not free to weigh the evidence, pass on the credibility of witnesses, or substitute its judgment of the facts for that of the jury." *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d 110, 113 (3d Cir. 1987).

Plaintiffs' motion for a new trial is governed by a similar standard. Rule 59(a) of the Federal Rules of Civil Procedure allows a party to seek relief from a judgment by filing a motion for a new trial. "New trials because the verdict is against the weight of the evidence are proper only when the record shows that the jury's verdict resulted in a miscarriage of justice or where

the verdict, on the record, cries out to be overturned or shocks our conscience." *Vargo v. Coslet*, 126 Fed. Appx. 533, 534 (3d Cir. 2005).

B. Application

1. Obviousness Standard

A reasonable jury could have found that the invention would have been obvious at the time of the invention to a person of ordinary skill in the art. The Patent Act provides that:

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains[.]

35 U.S.C. § 103(a); *Graham v. John Deere Co.*, 383 U.S. 1, 13-14 (1966). A finding of obviousness is a legal determination based upon factual inquiries. *Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1362 (Fed. Cir.1998). Such inquiries include determinations concerning: (1) the "scope and content of the prior art"; (2) "differences between the prior art and the claims at issue"; (3) "the level of ordinary skill in the pertinent art"; and (4) secondary considerations such as long-felt need, commercial success, and failure of others. *Graham*, 383 U.S. at 17-18; *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 415-17 (2007).

Where the invention is a combination of known elements from the prior art, as "most, if not all" inventions are, finding a motivation, teaching or suggestion to combine different references in the prior art is an important inquiry in order to avoid devaluating the invention based on hindsight. *KSR*, 550 U.S. at 418-19; *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008). However, the application of this test should be flexible and the motivation, teaching, or suggestion to combine references "need not always [come from] written references but may be found within the knowledge and creativity of

ordinarily skilled artisans." *Ortho-McNeil Pharmaceutical, Inc.*, 520 F.3d at 1365 (Fed. Cir. 2008). Thus, the suggestion to combine references may come from a variety of sources.

In light of the presumption that patents are valid, an alleged infringer must prove obviousness by clear and convincing evidence. *Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963 (Fed. Cir. 2006).

1. Level of Ordinary Skill in the Art

The jury could have reasonably looked to the testimony of the experts at trial to determine the education and experience of a person of ordinary skill in the art. Most of the experts had similar conceptions of what a person of ordinary skill would possess.

Plaintiffs and Defendants' experts had similar definitions of a person of ordinary skill in the art. Sandoz's expert Dr. Mayersohn testified that there were three possibilities of a person of ordinary skill in the art:

> One is a Bachelors in Pharmacy or Pharma D degree, at least a two-year residency or fellowship in the pharmaceutical industry or an academic setting providing similar training in pharmacokinetic principles and clinical pharmacology, or it's somebody with a Bachelors or Masters degree in Chemistry, Biology or Pharmaceutical Sciences or an M.D. degree and at least two years of experience in the pharmaceutical industry or an academic setting providing similar training in clinical pharmacology or at a higher level, a Ph.D. degree in Chemistry, Biology or Pharmaceutical Sciences or at least one year of industrial experience.

(Sept. 14, 2010 Trial Tr. at 144). Plaintiffs' expert, Dr. Guengerich testified that a person of ordinary skill in the art would have at least the following credentials:

> 1) A B.S. or M.S. degree in chemistry, biology, pharmacy or pharmaceutical sciences or an M.D. degree; *and* 2) at least two years of experience related to drug pharmacology in a pharmaceutical industry or an academic or medical setting.

(Sept. 8, 2010 Trial Tr. at 140) (emphasis added). Both definitions included at least a bachelor's degree in a science related to pharmacology and experience in the pharmaceutical industry, or its equivalent.

2. The Scope and Content of the Prior Art

The jury could have reasonably found that content of the prior art included all of the information set forth in the Facts section above. The parties presented all of this evidence at trial and the evidence may have been information of which a person of ordinary skill was aware.

3. The Differences between the Prior Art and the Patented Invention

Plaintiffs correctly point to two differences between the prior art and the patent: (1) while the FDA Guidances suggested that cytochrome p450 tests should be performed on drugs, nothing in the Guidances expressly or impliedly tells the reader to conduct them on metaxalone instead of the many other existing drugs; (2) the patent is directed towards a method of treatment, not the data obtained and none of the prior art explicitly suggests a method of treatment.

However, neither of these differences is so substantial that no reasonable jury could have found that the invention was obvious in light of the prior art. The jury could have found the first difference was obvious in light of a suggestion of success in the prior art and that the second difference was suggested in the FDA Guidances and amounted to nothing more than making knowledge patentable by patenting the process of imparting that knowledge to someone who might need it.

First, the FDA Guidances suggested that new drugs be tested for p450 activity in order to learn about the problems of drug-drug interactions and also recommended that old drugs be tested so that one could determine how they related to new drugs. (DTX 52 at 3, 5, 11). The Guidances explained that these tests were exceptionally rapid and routine, and explained that the

tests were important because when two substances are metabolized by the same cytochrome p450 pathways, "the potential for a drug inhibiting the metabolism is almost always present" and might also be present for different pathways. (DTX 51 at 4). The inventor contracted a lab that routinely conducts these types of tests to test whether the p450 enzymes most commonly involved in drug metabolism were involved in the metabolism of metaxalone. However, as Plaintiffs have pointed out, there is no suggestion in this document that *metaxalone* should be tested for cytochrome p450.

Nonetheless, there is a suggestion of success in the knowledge of the prior art when testing the metabolism of metaxalone with cytochrome p450. Plaintiffs' expert Dr. Guengerich testified that as far back as 1966, the person of skill in the art knew that metaxalone was metabolized by oxidation, that most metabolism by oxidation occurs in the liver, and that 85% of liver metabolism uses the cytochrome p450 system for metabolism. (Trial Tr. at 133-136, Sept. 8, 2010). This suggests that it is likely that cytochrome p450 is involved in the metabolism of metaxalone. Further, the 2003 Skelaxin drug label disclosed that metaxalone could impair a patient's ability to function if taken with a CNS depressant or alcohol, which Dr. Guengerich testified may have been due to the p450 system. (*Id.* at 140-42). Thus, not only could the jury have reasonably found a motivation in the prior art to attempt the testing, there was a suggestion of success in the knowledge in the prior art. *See Ortho-McNeil Pharmaceutical*, 520 F.3d at 1365.

Second, the fact that the patent is directed towards a method of treatment does not make this invention nonobvious as a matter of law. The method of treatment is simply to give the patient metaxalone, known in the prior art, and then inform the patient of the p450 interactions of metaxalone and another drug. ('566 patent, 64:45-66:30). The results of the testing themselves

are unpatentable because they are simply knowledge of the universe. The most obvious way to get around this unpatentability is to create a method of giving this information to a person who might have some use for it. That is exactly what the patentee did in drafting his claims. This is not nonobvious as a matter of law. Further, the FDA guidances mentioned that the p450 information should be included on the drug's package insert, which would, according to King's own theory of infringement, constitute informing doctors and patients of the information and thus recommended the informing step of the patent. (*See* DTX 52 at 13-16). Thus, this was in fact present in the prior art.

In sum, the evidence showed that the FDA recommended that drugs be tested for cytochrome p450 activity, that the procedures for carrying out such *in vitro* testing were well known and routine in the art and third party laboratories did them routinely, that the cytochrome p450 enzymes tested by the lab on behalf of the inventor were those known to be most commonly involved in drug metabolism, and that the FDA recommended that the results of such testing be included on the drug's package insert. Further, there was a suggestion in the art that such testing would be fruitful - metaxalone was metabolized by oxidation, which primarily occurs in the liver, whose metabolism occurs primarily from the cytochrome p450 isozyme system.

A reasonable jury could have used this evidence and legitimate inferences therefrom to conclude that the patent was obvious by clear and convincing evidence. The FDA suggested exactly the testing that Dr. Roberts ordered, and suggested the results be included on the label to *inform* the patient of that information. The fact that Dr. Roberts is the first person who happened to apply these teachings to metaxalone rather than another drug does not make the invention less obvious, particularly because there was a suggestion of success based on the known properties of

metaxalone. Metaxalone suggested success because it: (1) was metabolized by oxidation, a process that occurs primarily in the liver, which in turn metabolizes primarily using the cytochrome p450 isozymes; and (2) the 2003 Skelaxin label mentioned that CNS depressants and alcohol could impair a patient's ability to function when using metaxalone, which could have been because both were metabolized in the cytochrome p450 system.[2]

4. Secondary Considerations

While King put forth evidence on two secondary considerations, the jury could reasonably have found this evidence unpersuasive as evidence of any innovation in the invention. King put forth evidence of the licensing fee that King paid to Mutual for the patents as evidence of commercial success and the evidence of Sandoz's copying of its label as evidence of copying. The Court so charged the jury. (Sept. 16, 2010 Trial Tr., at 23).

The Court agrees with King that evidence of secondary factors "can be the most probative evidence of non-obviousness in the record, and [may] enable[] the court to avert the trap of hindsight." *Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294 (Fed. Cir. 2010). However, evidence of secondary factors must be related to the merits of the invention itself, i.e. what the invention offers beyond what was already available in the prior art. *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008). For example, to be evidence of the commercial success of the invention, large sales of a new golf club must be because of the innovative nature of the claimed club and not a celebrity endorsement or the well-designed club that it improved upon. In this case, the jury had ample reason to find that the commercial

[2] The Court agrees that the exact *results* of these studies, i.e. whether and to what degree metaxalone inhibited or induced a certain p450 isozyme, were unknowable before the study was conducted. However, the fact that there *would* be results was obvious. The results themselves were the conclusions of a routine lab work, not inventiveness. Additionally, the Court notes that Dr. Palumbo was not a person of ordinary skill in the art by either party's definition.

success and copying presented were not due to the '566 patent's invention, but to the invention it improved upon – metaxalone.

First, while King did purchase a license from Mutual for the patent, the evidence suggests that the cost of that license may have been unrelated to the claims of '566 patent. Plaintiffs' witness, James Green, admitted that the license predated the '566 patent, discussed its provisional application (whose disclosure may have little relation to the ultimate scope of the claims), and required a 5% royalty payment no matter what the scope of the claims that ultimately issued from the application. (Sept. 8, 2010 Trial Tr. at 18-23; Baton Decl., Ex. O at 5, PTX 140). Thus, the jury could have reasonably found that the payments were not directly related to the patent's claims.

In addition, there was evidence that the license was related to King's attempt to maintain a monopoly in the market on metaxalone and not the innovative nature of the patent. Mr. Green admitted that one of his concerns prior to the license was preventing generic competitors from entering the market and that, at the time, Mutual had proposed a generic product. He also admitted that King had managed to keep generics such as Mutual off the market until Sandoz's entry during the lawsuit. (Sept. 8, 2010 Trial Tr. at 23-31). A reasonable jury could have concluded that the impetus behind the license was to keep Mutual off the market. Further, the license is equally concerned with success securing the FDA's approval to relabel metaxalone and obtaining FDA approval for a new formulation. (Baton Decl., Ex. O at 5, PTX 140). The jury could have drawn a reasonable inference from this testimony that the license agreement had more to do with the monopoly value of metaxalone than with the merits of the patented invention itself. Thus, the jury could have disregarded this secondary consideration. *See Asyst Techs., Inc.*, 544 F.3d at 1316.

Second, the jury could have drawn the reasonable inference that Sandoz's copying of King's label had nothing to do with the invention itself and more to do with its intention to be the first generic on the market for metaxalone. It was undisputed at trial that: (1) generally the FDA requires generics to copy the label of the brand name; (2) that in certain situations the FDA allows a generic to "carve out" portions of the label if they are covered by patents; and (3) Sandoz copied King's label and did not ask the FDA to allow them to carve out any portion of it. (*See* PTX 39 at 1). However, the question for the jury was whether Sandoz's decision to decline to attempt the "carve out" was related to the innovative nature of the invention.

A reasonable jury could have drawn the inference, as even King's counsel suggested on closing, that Sandoz's copied the invention because it wanted to offer the first generic metaxalone product (Sept. 16, 2010 Trial Tr. at 130-134), and not because Sandoz found the information on the label to be vital or innovative.

Sandoz was able to obtain final approval more quickly because it did not propose a carve-out. (*See* PTX 39). Sandoz's request for final approval attempted to remove all obstacles to immediate approval: (1) it explained that there were no bioequivalency, CMC, or inspection compliance issues; and (2) it explained that its approval was not barred by any generic exclusivity period or litigation stays. The only apparent obstacle to approval was the labeling carve-out, which Sandoz seemed to be concerned would delay its launch:

> Sandoz understands, based on several informal discussions with your staff that the FDA is in the process of ascertaining whether to permit ANDA sponsors to "carve out" labeling information protected by the . . . '566 patent[]. . . . As a result of these pending matters, Sandoz understands that your office has generally advised ANDA applicants not to submit proposed Metaxalone labeling *until these issues have been resolved* and (if appropriate) *until a "carved out" labeling "template" has been developed by the agency*. Sandoz appreciates that *complex and difficult* scientific, medical, legal and policy questions are involved in deciding whether to allow a labeling "carve out."

> Sandoz also appreciates that the submission of proposed "carved out" labeling by those ANDA sponsors who have chosen to proceed by means of "(viii) statements" on . . . Orange Book patents before an agency decision on these matters would serve no useful purpose whatsoever. Importantly, however, the informal advice that Metaxalone ANDA applications *should not submit proposed labeling at this time* has no application to Sandoz, which does not seek approval based on "carved out" label.
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> . . . .
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> CONCLUSION
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> For these reasons, Sandoz respectfully requests that the enclosed Labeling Amendment be reviewed, and that this Sandoz ANDA receive final approval, *as expeditiously as possible*.

(PTX39 at 2) (emphasis added). In sum, the FDA had proposed a delay for other metaxalone applicants until the FDA could work out the difficult issues of a carve-out and Sandoz was able to avoid the delay because it did not seek a carved-out label.

A reasonable jury could conclude from this statement, as even King's counsel concluded, that the reason Sandoz did not request a carve-out was that it wanted to get the drug to market as soon as possible in order to be the first generic on the market. (*See* Sept. 16, 2010 Trial Tr. at 130-134). In other words, Sandoz did not really *want* to copy the label, it wanted to get a generic form of metaxalone on the market and copied the label because carving-out the patent would have caused further delay. Thus, if the jury so concluded, Sandoz's copying had nothing to do with wanting to copy the patent, which the label may have contained, but had everything to do with the value of metaxalone, a 50 year old product. *See Asyst Techs., Inc.*, 544 F.3d at 1316. Thus, the jury could have disregarded this factor because Sandoz did not copy due to the merits of claimed invention. *See id.*

Finally, even if the jury did not make these legitimate inferences, evidence of *two* of the many secondary considerations does not require the jury to find that the patent was nonobvious.

The presence of secondary considerations, while an important factor, does not require the jury to find an invention nonobvious. *See Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

In sum, the jury could have found that the invention was obvious to one of ordinary skill in the art because the prior art suggested that people of skill in the art should test the p450 metabolism of drugs, such testing was routine, and was likely to yield results for metaxalone. Further, the jury could have reasonably found that the evidence of secondary considerations was not related to the invention itself. Because the jury's verdict was supportable based upon the evidence, the Court denies King's motion for judgment as a matter of law and motion for a new trial.

III. CONCLUSION

For the foregoing reasons, King's motion for judgment as a matter of law or for a new trial is denied.

Dated: January 25, 2011

/s/ Garret E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J